

**REMARKS**

The Final Office Action mailed September 17, 2007, has been received and reviewed. Claims 1 through 12, 14 through 17, and 19 through 35 are currently pending in the application. Claims 1 through 12, 14 through 17, and 19 through 35 stand rejected. Applicants propose to amend claims 1, 15-17, and 30, and respectfully request reconsideration of the application as proposed to be amended herein.

**35 U.S.C. § 103(a) Obviousness Rejections**

Obviousness Rejection Based on U.S. Patent No. 4,806,343 to Carpenter et al., U.S. Patent No. 6,267,958 to Andya et al., U.S. Patent No. 4,816,440 to Thomson, U.S. Patent No. 5,861,284 to Nishimura et al., and U.S. Patent No. 5,128,242 to Arimura et al.

Claims 1 through 12, 14 through 17, and 19 through 35 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Carpenter et al. (U.S. Patent No. 4,806,343), Andya et al. (U.S. Patent No. 6,267,958), Thomson (U.S. Patent No. 4,816,440), Nishimura et al. (U.S. Patent No. 5,861,284), and Arimura et al. (U.S. Patent No. 5,128,242). Applicants respectfully traverse this rejection, as hereinafter set forth.

To establish a *prima facie* case of obviousness the prior art reference (or references when combined) **must teach or suggest all the claim limitations**. *In re Royka*, 490 F.2d 981, 985 (CCPA 1974); *see also* MPEP § 2143.03. Additionally, there must be “a reason that would have prompted a person of ordinary skill in the relevant field to combine the [prior art] elements” in the manner claimed. *KSR Int’l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1742, 167 L.Ed.2d 705, 75 USLW 4289, 82 U.S.P.Q.2d 1385 (2007). Finally, to establish a *prima facie* case of obviousness there must be a reasonable expectation of success. *In re Merck & Co., Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986). Furthermore, the reason that would have prompted the combination and the reasonable expectation of success must be found in the prior art, common knowledge, or the nature of the problem itself, and not based on the Applicant’s disclosure. *DyStar Textilfarben GmbH & Co. Deutschland KG v. C. H. Patrick Co.*, 464 F.3d 1356, 1367 (Fed. Cir. 2006); MPEP § 2144. Underlying the obvious determination is the fact that statutorily prohibited hindsight cannot be used. *KSR*, 127 S.Ct. at 1742; *DyStar*, 464 F.3d at 1367.

The 35 U.S.C. § 103(a) obviousness rejections of claims 1 through 12, 14 through 17, and 19 through 35 are improper because the cited references do not teach or suggest all of the claim limitations of the currently pending claims.

Independent claims 1, 15-17, and 30 have been amended to recite a polypeptide selected from the pituitary adenylate cyclase polypeptide/glucagon superfamily (or, in the case of claim 16, a pituitary adenylate cyclase polypeptide) that is stable under acidic conditions or in near neutral pH environments, and at temperatures of about or greater than 37°C. The relied upon references are all drawn to preserving biological activity of particular proteins during and after a freeze-drying (or lyophilization) process, particularly during the thawing, freezing and rehydration process. None of the references teaches or suggests preparing the particular stabilized polypeptide particles that are stable under acidic conditions or in near neutral pH environments, and at temperatures of about or greater than 37°C. As outlined in the Background section of Carpenter, freeze-drying creates very particular instability problems in proteins that lead to loss of activity. None of the cited references teaches or suggests overcoming problems with protein degradation under acidic conditions or in near neutral pH environments, and at temperatures of about or greater than 37°C., such as those encountered by implantable polypeptides.

As acknowledged in the Office Action, the combination of Carpenter, Andya, and Thomson do not teach or suggest polypeptides selected from the pituitary adenylate cyclase polypeptide/glucagon superfamily that are stable under acidic conditions or in near neutral pH environments, and at temperatures of about or greater than 37°C. To overcome this deficiency, the Examiner relies on Nishimura as disclosing a composition for stabilizing polypeptides with an amide at their C-terminal or a disulfide linkage in the molecule. (Office Action at pgs. 4-6). However, Nishimura is limited to a disclosure of a method of producing a fused parathyroid hormone having cysteine at its N-terminal and a cysteine-free peptide ligated to the N-terminal. Applicants respectfully submit that Nishimura does not overcome the deficiencies of the claims (as amended). In view of the foregoing, Applicants respectfully request withdrawal of the present rejection.

(Use when applicable) The nonobviousness of independent claims 1, 15-17, and 30 preclude a rejection of claims 2-12, 14, 19-29, and 30-35, which depend therefrom because a dependent claim is obvious only if the independent claim from which it depends is obvious. *See In re Fine*, 5 U.S.P.Q.2d 1596, 1600 (Fed. Cir. 1988), *see also* MPEP § 2143.03. Therefore, the Applicants request that the Examiner withdraw the 35 U.S.C. § 103(a) obviousness rejection to claims 1-12, 14-17, and 19-35.

### ENTRY OF AMENDMENTS

The proposed amendments to claims 1, 15-17, and 30 above should be entered by the Examiner because the amendments are supported by the as-filed specification and drawings and do not add any new matter to the application. Further, the amendments do not raise new issues or require a further search. Finally, if the Examiner determines that the amendments do not place the application in condition for allowance, entry is respectfully requested upon filing of a Notice of Appeal herein.

### CONCLUSION

Claims 1 through 12, 14 through 17, and 19 through 35 are believed to be in condition for allowance, and an early notice thereof is respectfully solicited. Should the Examiner determine

that additional issues remain which might be resolved by a telephone conference, he is respectfully invited to contact Applicants' undersigned attorney.

Respectfully submitted,



Edgar R. Cataxinos  
Registration No. 39,931  
Attorney for Applicants  
TRASKBRITT  
P.O. Box 2550  
Salt Lake City, Utah 84110-2550  
Telephone: 801-532-1922

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